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MATCHING LIMB PROTECTION SLEEVE FOR TOURNIQUET CUFF

This patent application is a Continuation In Part of U.S. Patent Application Number 09/ 378,034, filed 20 August 1999.

Field of the Invention

This invention generally pertains to surgical tourniquets. The invention particularly pertains to surgical tourniquet cuffs for encircling and applying pressure to patients' limbs in order to stop blood flow into the limbs and to limb protection sleeves matched to the cuffs for interposing between the limbs and the cuffs to help protect the limbs from cuff-related injuries during surgical procedures.

Background

Surgical tourniquet cuffs typically are applied to a patient's limb at a desired location and are then pressurized in order to stop the flow of arterial blood past the cuff, thereby establishing a bloodless filed in the portion of the limb distal to the cuff. The structure and function of some typical tourniquet cuffs of the prior art are described by Robinette-Lehmann in U.S. Patent No. 4,635,635, by Spence in U.S. Patent No. 4,979,953 and by McEwen in U.S. Patent Nos. 5,454,831 and 5,649,954. The pressure applied by such prior-art tourniquet cuffs is typically controlled by electronic tourniquet apparatus such as that described by McEwen in U.S. Patent No. 4,469,099 by McEwen and Jameson in U.S Patent No 5,607,447.

The bloodless surgical field created by a pressurized tourniquet cuff facilitates many types of surgical procedures performed on upper limbs and lower limbs, helps improve the quality and consistency of the surgical procedures, reduces the need for blood transfusions, and shortens surgical times. In certain kinds of surgical procedures, only the portion of the limb distal to the tourniquet cuff is anesthetized using a procedure called Bier block anesthesia or Intravenous Regional Anesthesia (IVRA); in such

procedures, the tourniquet cuff performs a dual function of keeping the anesthetic agent in the limb and keeping arterial blood out of the limb. Clinical practice involving the use of tourniquets in IVRA was recently summarized in a paper by Henderson et al. entitled "A North American Survey of Intravenous Regional Anesthesia" published in Anesthesia and Analgesia (1997; 85:858-863).

In an effort to reduce the probability of certain injuries to the soft tissues of the limb beneath a pressurized tourniquet cuff, some operators may elect to apply a soft bandage to the limb beneath the cuff. For example, in "Recommended Practices for Use of the Pneumatic Tourniquet", published by the Association of Operating Room Nurses (AORN) in the United States and effective as of January 1, 1999, it is noted that "The cuff should be applied to the extremity so that underlying skin and soft tissue are not unduly traumatized. Manufacturers' instructions may suggest that a soft, wrinkle-free padding (eg, cotton cast padding, stockinette) be wrapped smoothly around the limb as high on the extremity as possible, being careful not to pinch the skin folds where the tourniquet is applied. Once inflated the cuff should not be readjusted. Users must note that some tourniquet technology does not require padding."

In the prior art, soft bandages that have been used in conjunction with tourniquet cuffs have included sheet padding combined with a fluid-impervious layer and an adhesive tab as described by Hubbard et al. in U.S. Patent No. 4,406,281, as well as cast padding of the type wrapped around a broken limb before a cast is applied. Proper application of these soft bandages in conjunction with tourniquet cuff usage is very technique-dependent, requiring a trained and experienced applicator. Further, some types of padding may release loose fibers when applied, and these fibers may enter the surgical field and may clog the hook-and-loop fasteners that are typically used to secure tourniquet cuffs in position around the limb, thereby reducing the effective strength of these fasteners and creating a potential hazard. Also, the padding itself may take on a non-uniform shape around the limb, especially when an overlying tourniquet cuff is inflated. Finally, if too much soft bandage is used or if it is applied improperly, then hazards may arise because the level of pressure required in the tourniquet cuff to stop blood flow past the cuff may increase substantially, and the position of the cuff on the

limb may become unstable after inflation, increasing the likelihood that the cuff position may change significantly relative to the limb during use.

An alternative to the use of soft bandages and cast padding in the prior art has been to use tubular stockinette between the patient's limb and the tourniquet cuff. Typically, tubular stockinette is made and supplied in a wide range of predetermined 'lay-flat' widths, knits and materials. Tubular stockinette consists of a knitted textile having a substantially cylindrical shape in which some of the knitted threads either are elastic or are knitted in a manner that permits elastic stretching of the tubular shape. In appearance, tubular stockinette resembles the ankle portion of a sock or the leg portion of a nylon stocking. Elastic threads are included in some types of tubular stockinette to give them stretch and elastic characteristics that are a function of the type and number of elastic and non-elastic threads used in the knit and the knit pattern itself. In other types of stockinette that are knitted from non-elastic threads, the stretch and elastic characteristics of the stockinette are primarily determined by the type of knit. Two general advantages of using tubular stockinette under a tourniquet cuff, in comparison to overlapping soft bandages, are: tubular stockinette does not shed loose fibers which can enter the surgical field and clog cuff fasteners; and tubular stockinette does not produce as non-uniform a shape around the limb as soft bandages may do.

There are a number of limitations associated with such prior-art tubular stockinette. The most important limitation is that the pressure applied to the encircled limb by the tubular stockinette may be too high or too low. If the tubular stockinette is stretched excessively to fit around the limb at the desired cuff location, too high a pressure may result: in such situations, the pressure applied to the limb by the elastically stretched tubular stockinette may be sufficiently high to stop the flow of venous blood out of the limb and impair the flow of arterial blood into the limb.

Because of the concern about residual pressures that might be applied by tubular stockinette, one manufacturer of prior-art tourniquet cuffs and instruments (Zimmer, Warsaw IN) cautions on page 6 of the Operator and Service Manual for its A.T.S. 2000 Automatic Tourniquet System that "As an under padding, a section of stockinette may be used. The deflated cuff and any underlying bandages should be completely removed as

soon as tourniquet pressure is released. Even the slightest impedance of venous return may lead to congestion and pooling of blood in the operative field." Similar cautions and warnings about hazards related to the residual application of non-pneumatic pressure by underlying padding such as stockinette, as well as tourniquet cuffs, are given by other suppliers of tourniquet-related products and in the surgical literature.

Alternatively, if the tubular stockinette is not stretched at all, or if it is not stretched sufficiently at a desired cuff location, then the tubular stockinette may apply no pressure to the underlying limb and inflation of an overlying tourniquet cuff may then produce folding and wrinkling of the tubular stockinette material. This can cause soft tissue injuries resulting from pinching, folding and shearing of skin beneath the tubular stockinette, as well as causing other hazards arising from local anomalies in the pressure applied to the limb beneath the tubular stockinette by the inflated cuff and from the increased inflation pressure that may be required in the cuff to stop blood flow.

One commercial product is known in the prior art that combines tubular stockinette and a single-use tourniquet cuff in a single sterile package (Smith and Nephew Richards Inc., Memphis Tennessee). The tubular stockinette consists of a substantially cylindrical length of elastically stretchable knitted fabric that has been folded back on itself twice, so that by pulling the tubular stockinette up a limb to a desired cuff location, the tourniquet cuff can be applied over four layers of stockinette material. In products inspected by the inventor one common sleeve size was supplied with the 12" and 15" cuff sizes, thus that specific sleeve is not matched to a specific cuff, but to two cuffs of differing sizes for differing limb circumference ranges. Similarly, a second common sleeve size was supplied with the 24", 34", and 44" cuff sizes. The instructions enclosed with the cuff specify that the user should select a cuff large enough to have at least a suggested three-to-four inch overlap. In practical use, if the overlap is less than the suggested three-inch minimum at a desired limb location with a selected cuff, then the next larger cuff supplied by the manufacturer must be used. Thus the minimum limb circumference for that next larger cuff is effectively equal to the limb circumference that creates less than a three-inch overlap in the selected cuff. Accordingly, the effective limb circumference range of each cuff is (a) a maximum that

allows a three-inch overlap, and (b) a minimum that would allow a three-inch overlap in the next smaller cuff. Over part of these ranges, the stockinette sleeves provided with some of the cuffs inspected are too large, i.e. the circumference of the unstretched stockinette is greater than part of the range of circumferences of limbs on which the cuff may be applied. This is hazardous because, as noted above, the inventor has discovered that if the tubular stockinette is loose and not elastically stretched to apply a small pressure greater than a non-zero pressure threshold (determined in testing by the inventor of the present invention to be the minimum pressure at which a visible reduction in wrinkling and pinching was observed) at the desired cuff location on a limb prior to application of the tourniquet cuff, then the application and inflation of the cuff over the stockinette will produce folding and wrinkling of the underlying stockinette material, increasing the likelihood of soft tissue injuries due to pinching, folding and shearing of skin beneath the stockinette, as well as creating other surgical and IVRA-related hazards arising from local anomalies in the pressure applied to the limb and from the higher pressures that must be applied onto such stockinette by the encircling tourniquet cuff to stop blood flow in the underlying limb.

Another similar commercial product is known in the prior art that combines tubular stockinette and a single-use tourniquet cuff in a single sterile package ('Color Cuff II', Instrumed Inc., Woodinville, WA). The tubular stockinette consists of a substantially cylindrical length of elastically stretchable knitted fabric that has been folded back on itself once forming a two layer stockinette sleeve. However, as with the Smith and Nephew Richards product of the prior art, the sleeves supplied with some of the cuffs are not stretched on some limbs within the size range of the corresponding cuff. Also as with the Smith and Nephew Richards product of the prior art, a sleeve of the same size, and therefore having exactly the same unstretched circumference, is supplied with both the 24" cuff and the 34" cuff. Thus that specific sleeve is not matched to a specific cuff, but to two cuffs of differing sizes for differing limb circumference ranges. Instrumed also provides three different sizes of stockinette sleeves, each having a different circumference, for use with the six different sizes of non-sterile reusable tourniquet cuffs that it supplies. However no indication is given in the documentation

supplied to users of the cuffs of any correspondence between the sleeve sizes and cuff sizes, and no means is provided for users to match any specific sleeve sizes to any specific cuff sizes.

The pressure applied by a tubular stockinette to a limb of a given shape, circumference and tissue composition can be measured using a biomedical pressure transducer such as the one described by McEwen in U.S. Patent No. 4,869,265. Using such a transducer, it is has been found in tests conducted by the inventor that pressures from 0 mmHg to more than 60 mmHg can applied to limbs of varying circumferences and physical properties by prior-art tubular stockinettes of varying sizes, materials, knits and designs. For comparison, it has been found that an applied pressure as low as 30 mmHg can partially or completely obstruct venous blood flow, and that applied pressures lower than 60 mmHg can impede and partially block arterial blood flow. It is has been found in tests conducted by the inventor of the present invention that the pressure of a snugly applied tourniquet cuff can be as high as 25 mmHg.

With both the Smith and Nephew Richards and Instrumed products of the prior art, each different cuff size is indicated by a distinct color on the product label and on features permanently attached to the cuff. The sleeves, however, do not have any color or other matching or indicating features permanently attached. Once the sterile package is opened and the cuff and sleeve are separated, there is no indication to the user of the correct matching between the cuff and sleeve. This can be hazardous. For example, in one Smith and Nephew Richards product inspected by the inventor, an apparently incorrect sleeve size was included in the sterile, sealed package. Testing conducted by the inventor (as described in the preceding paragraph) revealed that at the maximum limb size accommodated by the cuff, the sleeve included in the package was extremely tight and applied a hazardous pressure to the limb. In this case, indicating means permanently attached to the sleeve may have alerted the user of the inappropriateness of the sleeve for the limb sizes accommodated by the cuff.

In the prior art, there is no known limb protection sleeve that matches a specific tourniquet cuff for application to limbs having circumferences between a minimum and a maximum circumference so that the sleeve, after application to a limb of minimum

circumference, stretches elastically to apply a small pressure greater than a non-zero threshold to the limb that is effective in reducing wrinkling and pinching of the limb, and so that the sleeve, after application to a limb of maximum circumference, applies a pressure to the limb that is less than a predetermined maximum pressure.

Brief Description of the Drawings

Fig. 1 is a pictorial representation of the preferred embodiment applied to a limb of a surgical patient.

Fig. 2 depicts the inner surfaces of four tourniquet cuffs of similar design and different sizes.

Fig. 3 shows the outer surface of one of the tourniquet cuffs depicted in Fig 2.

Figs. 4a, 4b and 4c show steps in the manufacture of a limb protection sleeve matching the tourniquet cuff shown in Fig. 3.

Fig. 5 shows four limb protection sleeves that match the four tourniquet cuffs depicted in Fig. 2.

Figs. 6a, 6b and 6c illustrate steps in a typical selection and application of a tourniquet cuff and matching limb protection sleeve to a patient's limb by a user.

Description of the Preferred Embodiment

The embodiment illustrated is not intended to be exhaustive or limit the invention to the precise form disclosed. It is chosen and described in order to explain the principles of the invention and its application and practical use, and thereby enable others skilled in the art to utilize the invention.

Fig. 1 depicts the preferred embodiment applied to a limb of a surgical patient. Limb protection sleeve 2 has been applied by a user to limb 4 along a portion of its length. Inflatable tourniquet cuff 6 is applied on top of a proximal portion of limb protection sleeve 2 to encircle the portion of sleeve 2 and limb 4 at a location desired by a

user. Cuff 6 is pneumatically connected to tourniquet instrument 8 through pneumatic port 10 and pneumatic tubing 12. Prior to the commencement of surgery, the portion of sleeve 2 distal to cuff 6 is folded back on top of cuff 6 by the user, as depicted in Fig. 6c. Tourniquet instrument 8 can then supply gas to tourniquet cuff 6 at a pressure sufficient to stop blood flow in limb 4 past cuff 6 and sleeve 2 for a time period sufficient for the performance of a surgical procedure.

Fig. 2 depicts the inner surfaces of tourniquet cuff 6, cuff 14, cuff 16 and cuff 18, which are pediatric tourniquet cuffs of different sizes that are distributed by Delfi Medical Innovations Inc. (Vancouver, Canada). Each of cuffs 6, 14, 16 and 18 is constructed of materials and in a manner generally similar to tourniquet cuffs of the prior art such as those described by McEwen in U.S. Patent Nos. 5,454,831 and 5,649,954.

Cuffs 6, 14, 16 and 18 shown in Fig. 2 have overall cuff width and cuff length dimensions as given in the table below. Also, for each of cuffs 6, 14, 16 and 18, the table shows the maximum limb circumference and the minimum limb circumference recommended by the distributor in the product literature and instructions provided for users. To assist users in easily identifying and differentiating among cuffs, the tie straps of different cuffs have different colors: cuffs 6, 14 16 and 18 have green, red, blue and black tie straps, respectively, as summarized in the table.

Cuff no. from Fig. 2 (and color of tie straps)	Overall Cuff Length (inches)	Overall Cuff Width (inches)	Recommended Minimum Limb Circumference (inches)	Recommended Maximum Limb Circumference (inches)
6 (green)	17.7	3.50	8.3	15.3
14 (red)	14.9	3.00	6.9	12.5
16 (blue)	10.6	2.25	4.9	8.3
18 (black)	7.5	1.50	3.5	5.6

Fig. 3 shows the outer surface of cuff 6 that faces away from limb 4 when cuff 6 encircles limb 4. The length 24 of cuff 6 is 17.7 inches and the width 26 of cuff 6 is 3.50 inches. Cuff 6 contains an inflatable chamber 28, the boundary of which can be seen in Fig. 2. Cuff 6 is designed to allow a user to encircle a patient's limb 4 at a desired location 30 so that a portion of inflatable chamber 28 of cuff 6 overlaps upon itself, and so that the user can secure encircled cuff 6 around limb 4 by fully engaging primary cuff fastener 32 to fastening strip 34 and by fully engaging secondary cuff fastener 36 to fastening strip 34. Complementary hook and loop materials, such as those known in the prior art as Velcro™, are permanently attached in positions shown in Figs. 2 and 3 to form primary cuff fastener 32, fastening strip 34 and secondary cuff fastener 36. Primary cuff fastener 32 and secondary cuff fastener 36 are formed of hook material, and fastening strip 34 is formed of loop material. The user may also tie together tie straps 20 and 22 as depicted in Fig. 1 to secure cuff end 38. When secured around limb 4 and inflated with gas from tourniquet instrument 8 at a sufficient pressure, cuff 6 can apply pressure around encircled limb 4 to stop the flow of arterial blood past cuff 6 into limb 4.

Cuff 6 is further designed to encircle limb 4 if limb 4 has a limb circumference greater than 8.3 inches and less than 15.3 inches at location 30, as specified in product literature and instructions provided by the distributor for the user. As illustrated in Figs. 1, 2 and 3, when cuff 6 is applied to limb 4 at location 30 having a circumference between the maximum and minimum circumferences recommended to the user, then the following four conditions occur: (1) a portion of inflatable chamber 28 overlaps upon itself around limb 4, thereby producing a uniform application of pressure around limb 4 when chamber 28 is inflated, (2) primary cuff fastener 32 can be fully engaged with fastening strip 34 by the user to secure cuff 6 around limb 4, (3) secondary cuff fastener 36 can also be fully engaged with fastening strip 34 by the user to secure cuff 6 around limb 4 independently of primary cuff fastener 32, and (4) tie straps 20 and 22 can be tied together by the user to secure cuff end 38.

If the circumference of limb 4 at location 30 is greater than the maximum circumference of 15.3 inches recommended to the user, then cuff 6 may not safely stop blood flow because of the occurrence of one or more of the following three conditions:

(1) primary cuff fastener 32 may not fully engage with fastening strip 34; (2) inflatable chamber 28 may not overlap upon itself around limb 4, thereby producing a non-uniform application of pressure around the limb when inflated; and (3) tie straps 20 and 22 may be obstructed by pneumatic port 10 of cuff 6, thereby preventing straps 20 and 22 from being tied together to secure cuff end 38.

Alternatively, if the circumference of limb 4 at location 30 is less that the minimum circumference of 8.3 inches, then the efficacy and safety of cuff 6 may be impaired by the occurrence of one or more of the following four conditions: (1) the width of cuff 6 may be excessive relative to the length of limb 4, resulting in hazardous application of pressure by cuff 6 to nerves and soft tissues near the knee or elbow joints of lower or upper limbs respectively; (2) the width of cuff 6 may be excessive relative to the length of limb 4, increasing the obstruction of potential surgical sites distal to cuff 6; (3) secondary cuff fastener 36 may not fully engage with fastening strip 34; (4) tie straps 20 and 22 may be obstructed by pneumatic port 10 of cuff 6, thereby preventing straps 20 and 22 from being tied together to secure cuff end 38.

Limb protection sleeve 2 of the preferred embodiment is designed for use with tourniquet cuff 6 by designing sleeve 2 to have the following four physical properties. First, sleeve 2 has a tubular and elastically stretchable shape, with an unstretched circumference of less than the minimum limb circumference recommended for cuff 6 so that it is elastically stretched when applied to a limb having the minimum recommended circumference and applies a minimum pressure of 2 mmHg, the low pressure threshold that the inventor has discovered in experiments is effective in reducing wrinkling and pinching. The level of 2 mmHg was determined in these tests to be the minimum pressure at which wrinkling and pinching of the tissue beneath cuff 6 began to be visibly reduced. The second physical property of sleeve 2 is that it can be elastically stretched in a radial direction to a circumference at least equal to the maximum limb circumference recommended for cuff 6. The third property of sleeve 2 is that, when elastically stretched and applied to a limb having the maximum recommended circumference, the maximum pressure applied to the underlying limb by sleeve 2 is less a predetermined maximum pressure threshold of 25 mmHg, determined by the inventor in experiments to be the

maximum pressure normally resulting from the snug application of cuff 6 alone to the limb. The fourth physical property of sleeve 2 is that, when applied to a limb having the maximum recommended circumference, the length of sleeve 2 is greater than the width of cuff 6, so that a portion of sleeve 2 can be folded over cuff 6 prior to the commencement of surgery, as shown in Fig. 6c.

Figs. 4a, 4b and 4c show how limb protection sleeve 2 is designed and made to match cuff 6 by having the physical properties described above. First, tubular stockinette 40 shown in Fig. 4a is produced by knitting type 18/1 ring spun cotton yarn fiber of natural color using 160 needles and 25 courses per inch. This results in tubular stockinette 40 having a circumference of 7.0 inches (twice a "layflat" width of about 3.5 inches) when not stretched in a radial direction, and having a maximum circumference of 26 inches (twice a "cross stretch" width of 13 inches) when stretched radially to the maximum. Stockinette 40 is cut to a length of 22.0 inches and folded back onto itself as shown in Fig. 4b, producing a tube having two layers and a length of 11.0 inches when unstretched. As depicted in Fig. 4c, the unfolded end is bias cut. This is done with the stockinette laid flat, to remove a piece having length 42 equal to 2.5 inches and width 44 equal to half of the layflat width of the stockinette, as shown in Fig. 4c. The unfolded end that includes the bias cut is then serge-sewn with green thread to produce limb protection sleeve 2 having a green edge 46. As indicated in Fig. 1, the bias cut of sleeve 2 allows sleeve 2 to be positioned as proximally as possible on limb 4 while still protecting a portion of limb 4 from port 10 and tubing 12. Sewn edge 46 increases the stability of dual-layer sleeve 2 under matching cuff 6 when cuff 6 is inflated and pressurized to stop blood flow, and the knit shape of sleeve 2 is compressible in response to the application of the pressure by matching cuff 6.

In certain applications (such as adult limbs with less restricted areas of surgical access), port 10 and tubing 12 may be located on the cuff midline near location 30 (see Fig. 1) rather than in a proximally protruding port portion of the cuff. In this case, the proximally protruding portion of the sleeve formed by the bias cut of dimensions 42 and 44 (shown in Fig. 4c) is not required and the sleeve may be positioned on the limb with the serge-sewn edge lying proximal or distal to the cuff. In either orientation the portion

of the sleeve extending distally from the cuff may be folded over the cuff as shown in Fig. 6c. Such sleeves are explicitly matched to the corresponding cuff by designing the sleeves to have the physical properties described above.To confirm that the design of sleeve 2 of the preferred embodiment, as described above, produces the necessary physical properties, sleeve 2 is applied to cover a simulated limb having a circumference equal to 15.3 inches, the maximum circumference recommended for matching cuff 6. A biomedical pressure transducer similar to that described by McEwen in U.S. Patent No. 4,869,265 is inserted between sleeve 2 and the simulated limb to measure the applied pressure. The maximum pressure applied by sleeve 2, as measured by the transducer in these design validation tests, is less than 15 mmHg, a pressure known from previous testing done by the inventor to be substantially less than the maximum non-pneumatic pressure of approximately 25 mmHg that typically can be produced by a tourniquet cuff when snugly applied to a limb by a user. Also, sleeve 2 is applied to cover a simulated limb having a circumference equal to 8.3 inches, the minimum circumference recommended for matching cuff 6, to confirm that sleeve 2 is elastically stretched after application, thus minimizing any residual wrinkling and irregularities, and to confirm using the same pressure transducer that the pressure applied to the simulated limb of minimum circumference by the elastically stretched sleeve is greater than the predetermined pressure threshold shown to begin to reduce visible wrinkling and pinching, and that the pressure is substantially less than 25 mmHg, the predetermined maximum pressure threshold. It has been demonstrated in testing (for example, see Tredwell SJ, Wilmink M, Inkpen K, and McEwen J: "Pediatric Tourniquets: Analysis of cuff/limb interface, current practice, and guideline for use" Journal of Pediatric Orthopaedics 2001, in press; and McEwen JA, Bailey K, Inkpen K, "Tourniquet safety: What type of padding should be used under the cuff to help prevent skin injuries?", in review for publication in *AORN Journal*) that a stretched sleeve such as sleeve 2 of the present invention applies a pressure greater than a predetermined minimum pressure threshold at the minimum recommended limb circumference such that that wrinkling and pinching is visibly reduced, and less than a maximum pressure threshold at the maximum recommended limb circumference, and that the application of such a pressure substantially reduces wrinkling and pinching of the soft tissues beneath tourniquet cuffs

such as cuff 6, as compared to other prior art cuffs applied over loose sleeves, over loose padding, or applied directly on the bare limb. The color of green edge 46 allows a user to visually match sleeve 2 to tourniquet cuff 6 having green tie straps 20 and 22. Although a common color is used in the preferred embodiment to associate sleeve 2 and cuff 6, it will be appreciated by those skilled in the art that alternate means might be used, such as marking numbers, letters or symbols directly on sleeve 2 and cuff 6 or on packages containing each. If cuff 6 and sleeve 2 are both designed as disposable medical devices, intended for use in only one surgical procedure and disposal after the procedure without re-use on another patient, then an alternate way of matching sleeve 2 and cuff 6 for the user is to package them together at time of manufacture, for example by putting them in the same bag or box.

Fig. 5 shows four sizes of limb protection sleeves 2, 48, 50 and 52 that are matched to tourniquet cuffs 6, 14, 16 and 18 respectively. Sleeves 48, 50 and 52 are designed, manufactured and validated as described above for sleeve 2, except that each has a different length, unstretched circumference, circumference at maximum stretch, and edge color. Sleeve 48 matches cuff 14 and is produced by: (a) knitting the same type of cotton fiber using 124 needles and 23 courses per inch, resulting in tubular stockinette having a circumference of 5.0 inches when not stretched in a radial direction, and having a maximum circumference of 18.0 inches when stretched radially to the maximum; (b) cutting the stockinette and folding it back onto itself to create a tube having two layers and a length of 9.5 inches, and (c) bias cutting an unfolded edge and serging the cut edge with red thread to produce red edge 54 matching the red tie straps of cuff 14. Sleeve 50 matches cuff 16 and is produced by: (a) knitting the same type of fiber using 70 needles and 22 courses per inch, resulting in tubular stockinette having a circumference of 3.0 inches when not stretched in a radial direction, and having a maximum circumference of 13.0 inches when stretched radially to the maximum; (b) cutting the stockinette and folding it back onto itself to create a tube having two layers and a length of 8.0 inches, and (c) bias cutting the unfolded edge and serging the cut edge with blue thread to produce blue edge 56 matching the blue tie straps of cuff 6. Sleeve 52 matches cuff 18 and is produced by (a) knitting the cotton yarn fiber using 40 needles and 21 courses per

inch, resulting in tubular stockinette having a circumference of 1.5 inches when not stretched in a radial direction, and having a maximum circumference of 7.0 inches when stretched radially to the maximum; (b) cutting the tubular stockinette and folding it back onto itself to create a tube having two layers and a length of 7.0 inches, and (c) bias cutting the unfolded edge and serging the cut edge with black thread to produce black edge 58 matching the black tie straps of cuff 18.

For each of limb protection sleeves 2, 48, 50 and 52 shown in Fig. 5, the table below summarizes the respective sleeve length, sleeve edge color, unstretched sleeve circumference, maximally stretched sleeve circumference, matching cuff, and the recommended minimum and maximum limb circumferences for sleeve and matching cuff.

Limb protection Sleeve (in Fig 5):	2	48	50	52
Sleeve length (inches)	11.0	9.5	8.0	7.0
Sleeve edge color	Green	Red	Blue	Black
Sleeve circumference:				
- Unstretched (in):	7.0	5.0	3.0	1.5
- Max. stretch (in):	26.0	18.0	13.0	7.0
Matching cuff (Fig. 2)	2	14	16	18
- Color of tie straps	Green	Red	Blue	Black
Recommended limb Circumferences for Cuff and sleeve :				
- Minimum (inches):	8.3	6.9	4.9	3.5
- Maximum (inches):	15.3	12.5	8.3	5.6

Figs. 6a, 6b and 6c illustrate steps in a typical selection and application of a tourniquet cuff and matching limb protection sleeve to limb 4 by a user. Prior to these steps, the user first observes the location 30 on limb 4 where it is desired to apply a tourniquet cuff and sleeve. The user then selects from the available sizes of cuffs the widest cuff that can: (a) fully encircle limb 4 at location 30 with a portion of the cuff overlapping upon itself, (b) allow the primary and secondary cuff fasteners to be fully engaged by the user, and (c) leave a safe distance between the distal edge of the selected cuff and joint 60 of limb 4 that is immediately distal location 30. The operating surgeon is responsible for determining this safe distance for each patient, to prevent injury to exposed nerves, vessels and soft tissue near joint 60. After the cuff is selected, the matching limb protection sleeve is selected; in the preferred embodiment, this is done by matching the color of the tie straps of the cuff to the color of the sewn edge of the sleeve. Figs. 6a, 6b and 6c indicate that cuff 6 and matching sleeve 2 have been selected for application at desired location 30 on limb 4. The user slides selected sleeve 2 onto limb 4 over location 30 as illustrated in Fig. 6a, and after application assures that sleeve 2 is free of wrinkles and that the colored edge 46 of sleeve 2 is positioned as shown in Fig. 6a to help protect limb 4 from port 10 and tubing 12. As shown in Fig. 6b, after application of sleeve 2, selected cuff 6 is wrapped snugly around the proximal portion of sleeve 2 and limb 4 at the desired location, while assuring that port 10 is positioned over sleeve 2 as shown. After snug application of cuff 6 by the user, the portion of sleeve 2 distal to cuff 6 is folded back over cuff 6 as shown in Fig. 6c. The operating surgeon then observes cuff 6 and sleeve 2 as applied, to assure that there is still a safe distance between joint 60 and applied cuff 6 and sleeve 2. The user can then connect tubing 12 to port 10 and inflate cuff 6 using tourniquet instrument 8 to stop blood flow for the performance of a surgical procedure. Immediately upon deflation of cuff 6, both cuff 6 and sleeve 2 are immediately removed from limb 4 to remove any residual restriction of blood flow.

It is to be understood that the invention is not to be limited to the details herein given but may be modified within the scope of the appended claims.

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